

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Not yet assigned
Group : Not yet assigned
Applicants : Jochen Wolffgramm
Application No. : Not yet assigned
Confirmation No. : Not yet assigned
Filed : Concurrently herewith
For : USE OF AGONISTS OF THE
GLUCOCORTICOSTEROID AND/OR MINERALO-
CORTICOSTEROID RECEPTORS, IN
PARTICULAR CORTICOSTEROIDS FOR THE
TREATMENT OF ADDICTION

New York, New York
May 9, 2001

Hon. Commissioner
for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to examining the above-identified
application, please amend the application as follows:

Kindly amend the application as follows:

IN THE SPECIFICATION

Please substitute new specification pages 1, 7 and
13 for former pages 1, 7 and 13. Applicants describe the
specific amendments to the specification using the bracket
and underline format in Appendix A, which is attached hereto.

Clean copies of the amended specification pages are attached as Appendix B.

IN THE CLAIMS*

Under the title heading "CLAIMS" and before claim 1 add the following words:

--What is claimed is:--.

Kindly cancel claim 1.

Kindly amend the claims as follows:

2. (Amended) The method according to claim 7, wherein the agonist is a corticosteroid or a pharmacodynamic equivalent thereof.

3. (Amended) The method according to claim 2, wherein the corticosteroid is selected from the group consisting of cortisol, cortisone, cortisone acetate, corticosterone, prednisolone, prednisone, prednylidene, methylprednisolone, triamcinolone, betamethasone, dexamethasone, paramethasone, fluorcortolone, deflazacort, cloprednol and fludrocortisone, a pharmacodynamic equivalent thereof or a combination thereof.

4. (Amended) The method according to any one of claims 2, 3 or 7, wherein the addictive disease is selected from the group consisting of opiate dependency, psychostimulant dependency, hallucinogen and entactogen dependency, amphetamine dependency, LSD dependency, and MDMA

* Applicants describe the specific amendments to the claims using the bracket and underline format in Appendix A, which is attached hereto.

(Ecstasy) dependency, nicotine addiction, cannabinoid dependency, cocaine addiction , "Crack" addiction, alcoholism or polytoxicomanic addiction.

5. (Amended) A pharmaceutical composition for the treatment of an addictive disease comprising:

- a. an addictive drug responsible for the addictive disease or a pharmacodynamic equivalent thereof; or a second addictive drug or the pharmacodynamic equivalent thereof; and
- b. at least one agonist selected from the group consisting of a corticosteroid receptor, a mineralo-corticosteroid receptor or a combination thereof.

6. (Amended) The pharmaceutical composition according to claim 5 wherein the addictive drug or a pharmacodynamic equivalent thereof is in a high dose and wherein the maintenance dose of at least one corticosteroid agonist is in the amount of 0.5-100 mg/day and 2 to 10 times higher amount for the initial dosage for a patient having a body weight of 60-80 kg.

7. (Amended) A method of treating an addictive disease caused by an addictive drug or in connection with the addictive drug comprising the step of administering a composition comprising:

- a. at least one agonist selected from the group consisting of a corticosteroid receptor, a mineralo-corticosteroid receptor, or a combination thereof; and
- b. the addictive drug or a pharmacodynamic equivalent thereof.

8. (Amended) The method according to claim 7, wherein a preparing treatment of at least one corticosteroid is administered prior to the treatment with the combination of agonist and addictive drug.

9. (Amended) The method according to claim 7, wherein the treatment with the composition of agonist and addictive drug is followed by the administration of an addictive drug or a pharmacodynamic equivalent thereof.

10. (Amended) The method according to claim 7, wherein the treatment with the composition of agonist and addictive drug is followed by a forced application of an addictive drug or a pharmacodynamic equivalent thereof.

Please add the following claim:

11. (New) The pharmaceutical composition according to claim 5, wherein the second addictive drug is an opioid.

REMARKS


Applicant has amended the specification to set forth a priority claim under 35 U.S.C. § 120 to an earlier filed application. Applicant has also amended the specification to recite the terms "BACKGROUND OF THE INVENTION", "SUMMARY OF THE INVENTION" and "DETAILED DESCRIPTION OF THE INVENTION".

Applicant has canceled claim 1 and added claim 11. Support for added claim 11 may be found, e.g., in claim 5 as originally filed. Applicant has amended claims 2-10 to conform to United States Patent and Trademark Office practice. None of these amendments adds new matter, none of these amendments narrow the scope of the claims, and

applicant reserves the right to prosecute any matter which may have been canceled through amendments of the claims herein.

For the convenience of the Examining Division, applicants have formatted the application to include line numbering. Applicant requests entry of the amendments and allowance of the claims.

Respectfully submitted,



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